DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 29, 2016

Covidien
Shannon Green
Sr. Regulatory Affairs Product Specialist
15 Hampshire Street
Mansfield, MA 02048

Re: K142128
Trade/Device Name: Kangaroo™ Enteral Feeding Syringe with ENFit Connector
Regulation Number: 21 CFR §876.5980
Regulation Name: Gastrointestinal Tube and Accessories
Regulatory Class: II
Product Code: PNR
Dated: January 15, 2015
Received: January 16, 2015

Dear Shannon Green,

This letter corrects our substantially equivalent letter of February 23, 2015.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

For Division

Douglas Silverstein -S
2016.09.29 08:02:46 -04'00'

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

Indications for Use

510(k) Number (if known): K142128

Device Name: Kangaroo™ Enteral Feeding Syringe with ENFit Connector

The Kangaroo™ Enteral Feeding Syringe with ENFit Connector delivers nutritional formula to the gastrointestinal system of a patient who is physically unable to eat and swallow. The feeding syringes are intended to be used in clinical or home care settings by users ranging from laypersons to clinicians (under the supervision of a clinician), to administer enteral nutrition. The syringe is intended for all age groups.

Prescription Use ____X_____ AND/OR Over the Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation

510(k) Summary
Kangaroo™ Enteral Feeding Syringe with ENFit Connector

In accordance with section 513(i) of the SMDA and as defined in 21CFR Part 807.92 this summary is submitted by:

Covidien
15 Hampshire Street
Mansfield, MA 02048
Date Prepared: July 31, 2014

a. Contact Person

Shannon Green
Sr. Regulatory Affairs Specialist
Covidien
Telephone: (508) 261-8587
Fax: (508) 261-8461

b. Name of Medical Device

Common Name: Gastrointestinal tubes with enteral specific connectors

U.S. FDA Classification Product Code: PIF

U.S. Regulation Description: Gastrointestinal tube and accessories, 21 CFR 876.5980

Proprietary / Trade Name: Kangaroo™ Enteral Feeding Syringe with ENFit Connector

c. Identification of Legally Marketed Device(s)

BD™ Oral/Enteral Syringe with BD UniVia™ Connection, K112434

d. Device Brief Description

The Kangaroo™ Enteral Feeding Syringe with ENFit Connector consists of disposable enteral feeding syringes that deliver formula to provide nutrition for those who do not have the ability to orally ingest food. The device incorporates a female ENFit connector for connection to an enteral access device.

e. Device Intended Use

The Kangaroo™ Enteral Feeding Syringe with ENFit Connector delivers nutritional formula to the gastrointestinal system of a patient who is physically unable to eat and swallow. The feeding syringes are intended to be used in clinical or home care settings by users ranging from laypersons to clinicians (under the supervision of a clinician), to administer enteral nutrition. The syringe is intended for all age groups.

f. Product Comparison Summary

The proposed and predicate enteral feeding syringes are intended for patients who require enteral feeding due to illness or injury which prevents normal chewing and swallowing. These products are enteral feeding syringes that have the same intended use, the same function, and the same general characteristics.

g. Nonclinical testing

- Biocompatibility testing has demonstrated the biological safety of parts of the medical device which may indirectly contact the patient.

- Stability testing evaluated the properties of the enteral feeding syringes after accelerated aging in support of the labeling.

- Dimensional analysis was conducted for critical dimensions of the Kangaroo™ Enteral Feeding Syringes with ENFit Connectors, in accordance with ISO 80369-3, Small-bore connectors for liquids and gases in healthcare applications – Part 3: Connectors for enteral applications. The testing demonstrates the proposed devices conform to Table B.2 of ISO 80963-3.

- Testing performed on the Kangaroo™ Enteral Feeding Syringes with ENFit Connectors included the items listed below, in accordance with ISO 80369-3, Small-bore connectors for liquids and gases in healthcare applications – Part 3: Connectors for enteral applications, using the test methods provided in ISO 80369-20, Small-bore connectors for liquids and gases in healthcare applications – Part 20: Common test methods. The testing demonstrates the proposed devices conform to the requirements of ISO 80963-3.

Test	**80369-3 Requirement is in:**	**80369-20 Test Method is in:**
Fluid Leakage	Clause 6.2	Annex C
Stress Cracking	Clause 6.3	Annex E
Resistance to separation from axial load	Clause 6.4	Annex F
Resistance to separation from unscrewing	Clause 6.5	Annex G
Resistance to overriding	Clause 6.6	Annex H
Disconnection by unscrewing	Clause 6.7	Annex I

- Minimum through diameter – flow testing was conducted and demonstrates the Kangaroo™ Enteral Feeding Syringes with ENFit Connectors exceeds the performance of the predicate device.

- The risk associated the misconnection of the ENFit connector has been assessed at length and captured in the following documents, which are located in Mater File 2258.
    - PG Lock Misconnection Data with FMEA 2014-01-9
    - 3595-0501-04 Enteral Connector Misconnection Assessment
    - Enteral Connection Risk Management Report Rev 2.0
    - PG Lock Misconnection Risk Assessment Report 041513

- Usability and human factors testing was conducted as part of the design of the ENFit connector, and is captured in the following document, which is located in the Master File 2258.
    - Human Factors Validation Study – Enteral Connectors Final Report

h. Clinical testing

Clinical evaluations were not relied upon for evidence of safety of effectiveness, or for a determination of substantial equivalence.

i. Conclusions

The information provided within this pre-market notification demonstrates that the Kangaroo™ Enteral Feeding Syringe with ENFit Connector has no difference that would affect the safety of effectiveness of the devices as compared to the predicate device.

End of Summary